Dear Stakeholders,
The text that is highlighted in yellow on pages 2 - 6 and 10 reflect the most recent changes agreed upon by the dialysis treatment advisory committee on April 15, 2014.

Health Facilities Regulation Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER XV - DIALYSIS TREATMENT CLINICS

6 CCR 1011-1 Chap 15

Section 1. STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1.5-103, 25-1.5-108, and 25-3-101, et seq., C.R.S.

1.2 A dialysis treatment clinic, as defined herein, shall comply with all applicable federal and state statutes and regulations, including but not limited to, the following:

(A) This Chapter XV.

(B) 6 CCR 1011-1, Chapter II, General Licensure Standards.

Section 2. DEFINITIONS

2.1 Department – The Colorado Department of Public Health and Environment, unless the context dictates otherwise.

2.2 Dialyzer Regeneration – The preparation for reuse of a single-use dialyzer in accordance with Section 6.5 of this Chapter.

2.3 Dialysis Treatment Clinic – A health facility or a department or unit of a licensed hospital that is planned, organized, operated and maintained to provide outpatient HEMODIALYSIS treatment ~~to,~~ or hemodialysis training for home use of hemodialysis equipment. ~~by, end-stage renal disease patients~~. {*Changed to conform with statutory definition amended by SB13-046}*

2.4 End-Stage Renal Disease – The stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or a kidney transplant to maintain life.

2.5 General Hospital – A facility licensed pursuant to 6 CCR 1011-1, Chapter IV, General Hospitals, that provides 24-hours per day, seven days per week inpatient services, emergency medical and surgical care, continuous nursing services, and necessary ancillary services to individuals for the diagnosis or treatment of injury, illness, pregnancy, or disability.

2.6 Governing Board – The board of trustees, directors, or other governing body in whom the ultimate authority and responsibility for the conduct of the dialysis treatment clinic is vested.

2.7 Hemodialysis Technician – A person who is not a physician or a registered nurse and who provides dialysis care.

2.8 INTERMEDIATE CARE PROVIDER – A NURSE PRACTITIONER, PHYSICIAN ASSISTANT OR ADVANCED PRACTICE NURSE PERFORMING WITHIN THE SCOPE OF PRACTICE SET BY THE COLORADO DEPARTMENT OF REGULATORY AGENCIES (DORA). THE TERM IS SYNONYMOUS WITH MID-LEVEL PROVIDER.

2.~~8~~9 National Credentialing Program – Any national program for credentialing or determining the competency of hemodialysis technicians that is recognized by the National Association of Nephrology Technicians/Technologists (NANT), or a successor association.

2.10 NON-END STAGE RENAL FAILURE – RENAL FAILURE THAT IS ACUTE BUT HAS NOT YET BEEN DIAGNOSED AS END-STAGE RENAL DISEASE.

Section 3. FEES

3.1 License fees. All license fees are non-refundable and shall be submitted with the appropriate license application.

(A) Initial license fee - $5,140 per facility.

(B) Renewal license fee - effective July 1, 2010, the fee shall be based upon the maximum number of a facility's operational procedure stations as set forth below.

1 - 12 stations	$1,750 per facility
13 - 23 stations	$2,750 per facility
24 or more stations	$3,750 per facility

(C) Change of ownership - change of ownership shall be determined in accordance with the criteria set forth in Chapter II, Part 2. The fee shall be $5,140 per facility.

Section 4. HOSPITAL AGREEMENT AND PUBLIC NOTICE REQUIREMENTS

4.1 Hospital Agreement

4.1.1 With the exception of general hospitals, any facility that applies for a dialysis treatment clinic license shall also have a written agreement with an affiliating general hospital that includes arrangements for ~~medical audit, utilization review,~~ emergency hospitalization and ~~infectious disease control~~ HOSPITAL TRANSFERS. The agreement may also provide for an organized medical staff in the affiliating

general hospital. Such agreement shall be submitted to and approved by the Department before issuance of any license.

~~4.1.2 A special medical advisory board composed of physicians specializing in nephrology and/or with clinical experience in dialysis may be appointed by the affiliating hospital for the purpose of medical audit and utilization review~~.
{*Language amended and moved to section 5.18}*

4.2 Public Notice Requirements

4.2.1 Each dialysis treatment clinic shall post a clear and unambiguous notice in a public location in the facility specifying that the clinic is licensed, regulated, and subject to inspection by the Department.

4.2.2 Each dialysis treatment clinic shall also inform consumers, either in the public notice described in this section or in written materials provided to consumers, that the consumer has a right to make any comments the consumer has concerning the clinic's services to either the clinic or the Department for consideration.

4.2.3 The consumer notice shall specify that any comments the consumer has concerning clinic services may be raised either orally or in writing.

Section 5. ORGANIZATION AND STAFFING REQUIREMENTS

5.1 Governing Board

5.1.1 A dialysis treatment clinic shall have a governing board that is formally organized with a written constitution or articles of incorporation and by-laws.

5.1.2 The governing board shall meet at regularly stated intervals, and maintain records of these meetings.

5.1.3 The governing board shall assume responsibility for the services provided by the clinic.

5.1.4 The governing board shall provide facilities, personnel, and services necessary for the welfare and safety of patients.

5.1.5 The governing board shall appoint the medical staff. Such appointments shall be made following consideration of the recommendations by the existing medical staff.

5.1.6 The governing board ~~should~~ SHALL appoint an administrative officer who is qualified by training and experience in hospital or clinic administration and delegate to that individual the executive authority and responsibility for the administration of the dialysis treatment clinic.

5.1.7 THE GOVERNING BOARD SHALL ADOPT A NATIONAL STANDARD FOR INFECTION CONTROL.

5.18 THE GOVERNING BOARD SHALL ESTABLISH A MECHANISM FOR THE PERFORMANCE OF MEDICAL AUDIT AND UTILIZATION REVIEW FUNCTIONS.

5.2 Administrative Officer

5.2.1 The administrative officer shall be responsible for the administration of the dialysis treatment center and shall maintain liaison between the governing board and medical staff.

5.2.2 The administrative officer shall ensure that the dialysis treatment clinic is formally organized to carry out its responsibilities. The plan of organization with the authority, responsibility, and functions of each category of all personnel ~~should~~ SHALL be defined clearly in writing.

5.2.3 The administrative officer shall be responsible for the development of dialysis treatment clinic policies and procedures for employee and medical staff use.

5.3 Medical Staff

5.3.1 All dialysis treatment clinics shall have an organized medical staff with written rules, regulations, and by-laws. The by-laws shall make provision for application, appointment, privileges, RESPONSIBILITIES, discipline, ~~control~~, right of appeal, attendance at medical staff meetings, committees, and professional conduct in the clinic.

5.3.2 A physician from the organized medical staff shall be appointed or elected as chief of staff.

5.3.3 The medical staff shall meet regularly and maintain written records of these meetings.

5.3.4 There shall be a medical audit committee to review systematically the work of the medical staff with respect to quality of medical care.

5.3.5 There shall be a medical records committee that supervises and appraises the quality of medical records according to the requirements contained in Section 6.3 of this chapter.

5.4 Nursing

5.4.1 Each clinic shall be under the direct supervision of a registered nurse with administrative capability and experience in hemodialysis.

5.4.2 The supervising nurse shall be responsible for staff assignments, policy and procedure development, records and reports, educational planning and overall patient care.

5.4.3 A registered nurse qualified in hemodialysis shall be on duty during the hours of the clinic's operation.

5.5 Hemodialysis Technicians

5.5.1 On and after January 1, 2009, a person shall not act as, or perform the duties and functions of, a hemodialysis technician unless that person has been credentialed by a national credentialing program and is under the supervision of a physician or registered nurse experienced or trained in dialysis treatment.

5.5.2 On and after January 1, 2009, a dialysis treatment clinic shall not allow any person to perform the duties and functions of a hemodialysis technician at or for the dialysis treatment clinic if the person has not been credentialed by a national credentialing program.

5.5.3 Nothing in this Section 5.5 shall prohibit a person enrolled in a hemodialysis technician training program from performing the duties and functions of a hemodialysis technician if:

(A) The person is under the direct supervision of a physician or a registered nurse experienced or trained in dialysis treatment, who is on the premises and available for prompt consultation or treatment; and

(B) The person receives his or her credentials from a national credentialing program within 18 months after the date the person enrolled in the training program.

5.6 All Clinic Personnel

5.6.1 Personnel records shall be kept on each of the clinic staff. These records shall include the employment application and verification of credentials.

5.6.2 On and after January 1, 2009, each dialysis treatment clinic shall confirm and maintain records for hemodialysis technician certification. Facilities shall provide a list to the department at the time of initial licensure, relicensure and upon request, with information including but not limited to the following:

(A) The names of all technicians employed by the clinic,

(B) The date the technician was credentialed by a national credentialing program or, if not credentialed, the date the technician enrolled in a ~~credentialing~~ training program AS LONG AS THE TECHNICIAN RECEIVES HIS OR HER CREDENTIALS FROM A NATIONAL CREDENTIALING PROGRAM WITHIN 18 MONTHS OF ENROLLMENT, and

(C) The name of the credentialing association.

5.6.3 The dialysis treatment clinic shall explain its purposes and objectives to all personnel. There ~~should~~ SHALL be written personnel policies and rules that

govern the conditions of employment, the management of employees, the types of functions to be performed, and the quality and quantity of clinic service. Following approval by the governing board, copies of such policies and rules ~~should~~ SHALL be ~~distributed~~ MADE AVAILABLE to all employees.

5.6.4 There ~~should~~ SHALL be sufficient qualified personnel in the clinic.

5.6.5 Additional personnel, including hemodialysis technicians, shall be assigned according to the needs of the patient and the clinic.

5.6.6 All persons assigned to the direct care of or service to patients ~~should~~ SHALL be prepared through formal education and on-the-job training in the principles, the policies, the procedures, and the techniques involved so that the welfare of patients will be safeguarded.

5.6.7 There ~~should~~ SHALL be an education program for all clinic personnel to keep the employees abreast of changing methods and new techniques in dialysis services.

~~5.6.8 All personnel should have a pre-employment physical examination and such interim examinations as may be required by the clinic administration or health service physician. The examining physician should certify that the employee, before returning from illness to duty, is free from infectious disease. Employment health policies should be arranged so personnel are free to report their illness without fear of income loss.~~ {C*ontrary to CDC guidelines. Replaced with § 6.4.3.below*}

Section 6. PATIENT/CLINICAL FUNCTIONS

6.1 Hemodialysis Services

(A) A DIALYSIS TREATMENT CLINIC SHALL NOT PROVIDE OUTPATIENT HEMODIALYSIS TREATMENT TO A NON-END-STAGE RENAL DISEASE PATIENT WITHOUT A REFERRAL FOR TREATMENT FROM A BOARD-CERTIFIED OR BOARD-ELIGIBLE NEPHROLOGIST LICENSED AS A PHYSICIAN IN COLORADO. WHEN MAKING THE REFERRAL, THE NEPHROLOGIST AND OTHER LICENSED PHYSICIANS WHO CARED FOR THE PATIENT IN THE HOSPITAL SHALL USE THEIR PROFESSIONAL JUDGMENT TO DETERMINE WHEN THE PATIENT NO LONGER REQUIRES HOSPITALIZATION AND MAY RECEIVE OUTPATIENT DIALYSIS. [M*andated by SB13-046]*

6.1.1 Water Supply

(A) The clinic's water supply system shall be from a municipal water supply system or other system that meets the criteria established by the Department in ~~the~~ REGULATION NO. 11 OF THE WATER QUALITY CONTROL COMMISSION, Colorado Primary Drinking Water Regulations, ~~5 CCR 1003-1~~ 5 CCR 1002-11. {*5 CCR 1003-1 was repealed effective March 1, 2014 and replaced with 5 CCR 1002-11*}

(B) Water used in hemodialysis procedures shall be further treated before use in dialysis machines. Dialysis treatment clinics shall follow a recognized method of treatment.

6.2 Clinical Laboratory

6.2.1 Clinical laboratory services shall be provided within the facility or by contract.

6.2.2 Contracted services shall meet the standards established herein.

6.2.3 Staffing and Organization

(A) The laboratory shall be under the supervision of a physician, certified in clinical pathology, either on a full-time, part-time, or consulting basis. The pathologist shall provide, at a minimum, monthly consultative visits.

(B) Emergency laboratory services shall be made available whenever needed.

(C) All laboratory work shall be ordered by a physician or a person authorized by law to use the results of such findings.

6.2.4 Facilities and Equipment

(A) There shall be adequate space within the facility for the laboratory.

(B) There shall be adequate storage space for supplies.

(C) Workbench space shall be ample, well lighted, and convenient to sink, water, and electrical outlets as necessary.

(D) All laboratory equipment shall be in good working order, be routinely checked and be precise in terms of calibration.

(E) A schedule of preventive maintenance shall be set up for all laboratory equipment.

6.2.5 Policies and Procedures

(A) A manual outlining all procedures performed in the laboratory shall be completed and readily available for reference.

(B) The conditions and procedures for referring specimens to another laboratory shall be in writing and available in the laboratory.

6.2.6 Clinical Laboratory Records

(A) A record of all preventive maintenance, repair, and calibration shall be kept on each item of laboratory equipment.

(B) A record system shall be established which ensures that laboratory specimens are adequately identified, properly processed, and permanently recorded.

(C) Duplicate copies of all reports shall be kept in the laboratory in a manner that permits ready identification and accessibility, for at least four years plus the current fiscal year.

6.3 Medical Records

6.3.1 Only members of the medical/house staff or other persons authorized by state law or regulation shall write or dictate medical histories and physical examinations.

6.3.2 A complete medical record shall be maintained on every patient registered in the dialysis treatment clinic. Each patient's record shall include:

(A) Sufficient information to properly identify the patient including clinic identification assigned to patient,

(B) Date and time of each treatment session,

(C) Original copies of any clinical test results including reports of tests referred to another laboratory,

(D) Initial diagnosis, ~~and~~

(E) Secondary diagnosis and complications as necessary, AND

(F) EVIDENCE OF COORDINATION OR CONTINUITY OF CARE WITH OTHER SERVICE PROVIDERS (E.G. HOSPITALS, LONG TERM CARE FACILITIES, HOME AND COMMUNITY SUPPORT SERVICES AGENCIES, OR TRANSPORTATION PROVIDERS) AS NEEDED TO ASSURE THE PROVISION OF SAFE CARE.

6.3.3 All orders for diagnostic procedures, treatments, and medications shall be signed by the physician submitting them and entered in the medical record in ink, in type or electronically. The prompt completion of a medical record shall be the responsibility of the attending physician.

6.3.4 Authentication of the order may be by written signature, identifiable initials, computer key, or electronic verification. ~~The use of rubber stamp signatures is acceptable under the following strict conditions:~~

~~(A) The physician whose signature the rubber stamp represents is the only one who has possession of the stamp, is the only one who uses it, and~~

~~(B) The physician places in the administrative offices of the clinic a signed statement to the effect that he is the only one who has the stamp and is the only one who uses it.~~ {*Obsolete language*}

6.3.5 Each dialysis treatment center shall provide a medical record room or other suitable medical record facility OR AREA with adequate supplies and equipment. Medical records ~~should~~ SHALL be stored safely to provide protection from loss, damage, and unauthorized use.

6.3.6 Medical records for individuals 18 years of age and older shall be preserved as original records, on microfilm or computer disc for no less than ten years from the most recent patient care usage, after which time records may be destroyed at the discretion of the clinic. Medical records for minors under the age of 18 shall be preserved for the period of minority plus ten (10) years.

6.3.7 The clinic shall establish procedures for notifying patients whose records are to be destroyed before the destruction of such records.

6.3.8 The sole responsibility for the destruction of all medical records shall lie with the clinic involved but in no case shall records be destroyed before consultation with legal counsel.

~~6.3.9 Nothing in this section shall be construed to affect the requirements for the destruction of public records as set forth in Section 24-80-101,et seq., C.R.S.~~ {*Unnecessary section because it only applies to state government*.}

6.4 Infection Control

6.4.1 The dialysis treatment clinic shall have a multi-disciplinary infection control committee charged with the responsibility of investigation and recommendations for the prevention and control of infection in the clinic.

6.4.2 The multi-disciplinary infection control committee shall be responsible for all clinic policies and procedures related to infection control including the following:

(A) The isolation of patients with specific infectious diseases and protective isolation of appropriate patients,

(B) The control of routine use of antibiotics and adrenocorticosteroids,

(C) ~~The review and revision of policies and procedures for infection surveillance and control.~~ THE REVIEW AND REVISION OF CLINIC POLICIES AND PROCEDURES TO ENSURE COMPLIANCE WITH THE GOVERNING BOARD'S CHOSEN NATIONAL STANDARD FOR INFECTION CONTROL.

(D) Presentation of ORIENTATION AND in-service education programs on the control of infection, and

(E) The reporting of infectious diseases as required by applicable state and federal laws and regulations.

~~6.4.3 For the committee to carry out its responsibilities the following are highly recommended standards:~~

~~(A) Meet at least monthly, and more frequently if the surveillance committee so indicates.~~

~~(B) Plan an agenda that includes:~~

~~(1) Review of significant features of the monthly report.~~

~~(2) Review of one major control policy (and related procedures) area each month in the light of newest available information and the clinic's current practice.~~ {*Stricken because "highly recommended" standard is not enforceable. Unenforceable standards do not belong in regulation*.}

6.4.3 THE DIALYSIS TREATMENT CLINIC SHALL IMPLEMENT POLICIES AND PROCEDURES TO PROHIBIT CLINIC PERSONNEL WITH A COMMUNICABLE OR CONTAGIOUS DISEASE FROM PROVIDING DIRECT PATIENT CARE WHEN IT CAN BE ~~REASONABLY ASSUMED~~ DETERMINED THAT SUCH CONTACT MIGHT RESULT IN TRANSMISSION OF THE DISEASE.

6.5 Dialyzer Regeneration

6.5.1 Regeneration shall not be permitted on dialyzers used for hepatitis antigen positive patients.

6.5.2 Prior to individual dialyzer regeneration, a physician shall inform the patient involved of the possible complications and hazards along with the possible benefits of such regeneration.

6.5.3 No patient shall be denied access to dialysis in the clinic as a result of that patient's refusal to permit regeneration of his or her dialyzer. The clinic shall document all instances where a patient refuses to permit regeneration.

6.5.4 Staffing and Training

(A) The clinic shall provide training for all personnel in the protocols and procedures for regeneration at the time of employment and at least annually thereafter.

(B) The clinic shall document the qualifications of the personnel responsible for the regeneration process along with the protocols for training said personnel.

6.5.6 Policies and Procedures

(A) The clinic shall establish polices to ensure the safety of employees when using disinfecting agents and procedures to address accidents and disinfectant spillage.

(B) Quality control procedures shall be established and documented in the facility procedure manual.

(C) The infection control committee, if one exists, shall approve all quality control procedures.

6.5.7 Quality Control

Quality control procedures shall include, but not be limited to, the following:

(A) Each dialyzer to be reused shall be clearly and indelibly labeled with the patient's name and other unique identifying information before the initial use.

(1) At each subsequent use, the label shall be checked by two (2) separate individuals, preferably the dialysis staff member and the patient.

(B) The number of uses shall be recorded in a reuse record maintained for each dialyzer and in the patient's permanent dialysis record.

(C) Water used to formulate cleaning solution and to rinse dialyzers shall be passed through a reverse osmosis membrane, ultra filtration membrane or a submicron filter (0.45 micron) which is appropriately maintained. This water shall contain less than 200 bacteria per ml. and shall be checked monthly by bacteriologic sampling of the source water outlet in the reprocessing area. If such sampling reveals bacterial counts that exceed this limit, the clinic shall implement corrective measures and do weekly sampling until the result returns to less than 200 bacteria per ml. The clinic shall maintain a record with the results of all samples.

(D) Each dialyzer shall be disinfected with an effective agent and each disinfection shall be documented. If formaldehyde is used as the disinfecting agent, there shall be a minimum concentration of 2% in both the blood and dialysate compartments, and the minimum exposure time shall be no less than 24 hours.

(E) Disinfection shall be monitored. All febrile reactions during dialysis with new or used dialyzers shall be documented in the patient's record.

(F) Blood and dialysate cultures shall be done on all patients experiencing febrile reactions. The results of those cultures shall be documented in the dialysis record.

(G) There shall be documentation of the addition of effective disinfectant concentrations in the dialyzer to be reused.

(H) Effective disinfectant removal from each dialyzer immediately prior to reapplication shall be documented. There shall be validation on a monthly basis regarding the effectiveness of the disinfectant removal.

(I) All other potentially toxic substances added during any part of the reprocessing procedure shall be removed and the removal documented by routine testing and/or validation studies, as appropriate.

(J) The effectiveness of the reprocessing procedure shall be documented before each subsequent use of each dialyzer.

(1) For hollow fiber dialyzers, a hollow fiber bundle volume (HFBV) of not less than 80% of the initial HFBV, measured at 0+10 mm of HG transmembrane pressure, shall be maintained.

(2) For parallel plate or coil dialyzers, small molecular clearance tests shall be performed during or after each use. Performance less than 90% of original capacity shall not be permitted.

(K) Blood leaks during the use of either new or reprocessed dialyzers shall be documented. If the blood-leak rate of used dialyzers exceeds that of new dialyzers, each used dialyzer shall be pressure-tested for possible blood compartment leak before reuse.

(L) Dialyzers shall be discarded unless the following criteria are met at the time the dialyzer is to be used on the patient:

(1) The dialyzer has no cracked or broken parts,

(2) The dialyzer appears clear and free of dissolved or residual blood manifest by a brownish or pinkish tinge, and

(3) Headers are visibly free of all but small peripheral clots.

6.5.8 Facilities

The clinic shall designate a separate room for dialyzer regeneration that meets all of the following criteria:

(A) Is equipped with a counter and counter sink unless equipped with an appropriate flushing system,

(B) Contains approved hand-washing facilities and storage cabinets,

(C) Contains separate clean and soiled areas. Regenerated dialyzers shall be maintained only in the clean area,

(D) Is ventilated with fresh air at a minimum rate of six (6) air changes per hour or locally exhausted. Air shall not be recirculated through the ventilating system except at those times when processing is not taking place,

(1) If general exhaustion of the room is selected, as opposed to local exhaustion, the site of exhaustion shall be, at a maximum, six (6) inches from floor level. (Note: formaldehyde gas is heavier than air.)

(E) Is lighted to a level of 50-foot candles throughout. Light levels at the work surfaces shall be 100-foot candles, and

(F) Contains storage space for supplies and regenerated dialyzers proportional to the number of patients in the unit.

6.5.9 PATIENT CARE [*New section applicable to both acute and chronic patients]*

(A) ADMISSION POLICIES AND PROCEDURES

(1) THE FACILITY SHALL DEVELOP POLICIES AND PROCEDURES REGARDING PATIENT ADMISSION CRITERIA.

(2) A PATIENT MEDICAL HISTORY AND CURRENT HEALTH STATUS INFORMATION SUFFICIENT TO DETERMINE APPROPRIATENESS FOR ADMISSION SHALL BE OBTAINED AND RECORDED PRIOR TO OR ON THE DATE OF ADMISSION.

(3) THE RECEIVING ATTENDING PHYSICIAN AND DESIGNATED REGISTERED NURSE SHALL REVIEW EACH PATIENT'S RECORDS TO DETERMINE THE APPROPRIATENESS OF THE ADMISSION.

(B) PATIENT CARE POLICIES

THE FACILITY SHALL HAVE WRITTEN PATIENT CARE POLICIES RELATING TO ALL AREAS OF CARE, WHICH ARE APPROVED BY THE MEDICAL DIRECTOR AND GOVERNING BODY. THE PATIENT CARE POLICIES SHALL BE REVIEWED PERIODICALLY TO DETERMINE EFFECTIVENESS, BUT AT LEAST ANNUALLY.

(C) PATIENT CARE PLAN

(1) PRIOR TO THE FIRST DIALYSIS TREATMENT, THERE SHALL BE AN INITIAL NURSING ASSESSMENT TO DETERMINE EACH PATIENT'S NEEDS AND ENSURE THAT SAFE, APPROPRIATE CARE CAN AND WILL BE PROVIDED UNTIL A PATIENT CARE PLAN IS DEVELOPED.

(2) WITHIN THIRTY (30) DAYS OF ADMISSION OR 13 TREATMENTS, WHICHEVER IS LONGER, THE FACILITY SHALL DEVELOP A WRITTEN PATIENT CARE PLAN THAT INCLUDES TREATMENT GOALS.

(3) THE CARE PLAN SHALL BE INDIVIDUALIZED TO REFLECT THE PATIENT'S ONGOING MEDICAL, PSYCHOLOGICAL, SOCIAL, DIETARY AND FUNCTIONAL NEEDS. THE CARE PLAN SHALL BE REVIEWED AND UPDATED AS INDICATED BY ANY CHANGE IN THE PATIENT'S MEDICAL, NUTRITIONAL OR PSYCHOSOCIAL STATUS, OR AT LEAST ANNUALLY.

(4) ALL PATIENT CARE PLANS SHALL INCLUDE EVIDENCE OF THE PATIENT'S (OR PATIENT'S LEGAL REPRESENTATIVE'S) INPUT AND PARTICIPATION, UNLESS THEY REFUSE TO PARTICIPATE. AT A MINIMUM, THE PATIENT CARE PLAN SHALL DEMONSTRATE THAT THE CONTENT WAS REVIEWED WITH THE PATIENT OR THE PATIENT'S LEGAL REPRESENTATIVE.

(D) MEDICAL OVERSIGHT AND ON-CALL COVERAGE

(1) THE FACILITY SHALL ENSURE THAT THE CARE OF EACH DIALYSIS PATIENT IS UNDER THE CONTINUING OVERSIGHT OF A NEPHROLOGIST.

(2) A NEPHROLOGIST OR LICENSED INTERMEDIATE CARE PROVIDER WITH EDUCATION AND EXPERIENCE IN THE CARE OF PATIENTS WITH ACUTE AND CHRONIC KIDNEY FAILURE SHALL BE ON CALL DURING THE FACILITY'S OPERATING HOURS. A ROSTER OF ON-CALL PROVIDERS SHALL BE POSTED AT THE NURSES' STATION.

Section 7. SANITARY ENVIRONMENT

7.1 Housekeeping Services

7.1.1 Each dialysis treatment clinic shall establish organized housekeeping services that are planned, operated, and maintained to provide a pleasant, safe and sanitary environment. The services ~~should~~ SHALL be under the supervision of a person competent in environmental sanitation and management.

7.1.2 There shall be specific written procedures for appropriate cleaning of the physical plant and equipment, giving special emphasis to procedures that apply to infection control. Policies shall be established to provide supervision and training programs for housekeeping personnel.

7.1.3 Solutions, cleaning compounds, and hazardous substances shall be properly labeled and stored in safe places. Paper towels, tissues, and other supplies shall be stored in a manner to prevent their contamination prior to use.

7.1.4 Dry dusting and sweeping are prohibited.

7.1.5 All rubbish and refuse containers shall be impervious and tightly covered. Carts used to transport rubbish and refuse shall be constructed of impervious materials, shall be enclosed, and shall be used solely for this purpose. Accumulated waste material shall be removed at least daily.

7.2 Insect, Pest and Rodent Control

7.2.1 Written policies and procedures shall provide for effective control and eradication of insects, pests, and rodents.

7.2.2 The clinic shall have a pest control program provided by maintenance personnel or by contract with a pest control company using the least toxic and least flammable effective pesticides.

7.2.3 The pesticides shall not be stored in patient or food areas and shall be kept under lock, and only properly trained responsible personnel shall be allowed to apply insecticides and rodenticides.

7.2.4 Screens or other approved methods shall be provided on all exterior openings and the structure shall be maintained to prevent entry of rats or mice through cracks in foundations, holes in walls, around service pipes, etc.

7.3 Waste Disposal

7.3.1 The clinic shall make provision for proper and safe disposal of all types of waste products.

7.3.2 All personnel shall wash their hands thoroughly after handling medical waste products.

7.3.3 All sewage shall be discharged into a public sewer system, or if such is not available, shall be disposed of in a sanitary manner consistent with applicable state laws and regulations.

7.3.4 No exposed sewer line shall be located directly above working, storing, or eating surfaces in kitchens, food storage rooms, or where medical supplies are prepared, processed or stored.

7.3.5 All garbage, not treated as sewage, shall be collected in watertight containers in a manner that prevents it from becoming a nuisance, and shall be removed from the facility on a scheduled basis per public or contracted service.

7.3.6 A sufficient number of sound watertight containers with tight-fitting lids, to hold all garbage that accumulates between collections, shall be provided. Lids shall be kept on the containers. Any racks or stands shall be kept in good repair.

7.3.7 Garbage containers shall be cleaned each time they are emptied. (Single service container liners are recommended.) A paved storage area for the containers ~~should~~ SHALL be provided.

Section 8. PHYSICAL PLANT AND EQUIPMENT

8.1 Reserved

8.2 Maintenance

8.2.1 The building and mechanical programs shall be under the direction of a qualified person informed in the operations of the clinic and in the building structures, their component parts and facilities.

8.2.2 There shall be written policies and procedures for an organized maintenance program to keep the entire facility, including equipment, in good repair and to provide for the safety, welfare, and comfort of the occupants of the building(s).

8.3 Central Medical Supply

8.3.1 Each dialysis treatment clinic shall provide central supply services with facilities for processing, sterilizing, storing and dispensing supplies and equipment if supplies and equipment are not all sterilized by the manufacturer.

8.3.2 This service shall be separated physically from other areas of the clinic and shall include areas designated for the following:

(A) Receiving,

(B) Cleaning and processing,

(C) Sterilizing, if applicable,

(D) Storing clean and sterile supplies, and

(E) Storing bulk supplies and equipment.

8.3.3 A two-compartment sink, with counter or drain board and knee-or-wrist action valves, shall be provided in the cleaning area.

8.3.4 Adequate cabinets, cupboards, and other suitable equipment shall be provided for the processing of materials and for the storage of equipment and supplies in a clean and orderly manner.

8.3.5 Ventilation to the central supply area may be supplied from the general ventilation system, if properly filtered. The flow of air ~~should~~ SHALL be from the clean areas toward the exhaust in the soiled area. Exhausts shall be installed over sterilizers to prevent condensation on walls and ceilings. In the case of new facility construction, or modification of an existing facility, the flow of air shall be from the clean areas toward the exhaust in the soiled area.

8.3.6 Central medical supply services shall be organized as a unit under the immediate supervision of a person who is competent in management, asepsis, supply processing, and control methods. Sufficient supporting personnel shall be assigned to the unit and properly trained in central medical supply services.

8.4 Compliance with FGI Guidelines

8.4.1 Effective July 1, 2013, all dialysis treatment clinics shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each

facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines